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Description

The present invention relates to prosthetic heart valves. More particularly, the present invention is directed to heart valves of the type including a sewing ring to be permanently mounted in the heart and a removable valve member mounted in the sewing ring.

Typical prior art prosthetic heart valves are essentially permanently installed. Both mechanical valves and tissue valves are sutured into place. These valves are further fixed in place by ingrowth of tissue on the perimeter.

Of course it is not possible to design a prosthetic heart valve that will last forever. All valves have some natural life. At the end of the life cycle, it is appropriate to remove the prosthetic valve and replace it with a successor valve. Additionally, children require replacement of valves because of changes in their heart size as they grow.

The replacement of the heart valve can be difficult. Because of tissue ingrowth, the surgery required to remove the implanted heart valve and implant the successive replacement can be more complex than the original implantation operation.

Attempts have been made to ease this replacement by providing heart valves with replaceable elements. For example, United States Patents 3,997,923, 4,680,031 and 4,705,516 disclose attempts to solve this problem by having a removable valve member snapped or threaded into a permanent sewing ring. This type of attachment mechanism is susceptible to overgrowth by tissue, which impedes removal.

A further goal of prosthetic heart valves is to increase blood flow through the valve. A valve which offers the least obstruction to the flow of blood maximizes cardiac output. Previous sewing rings have considerably narrowed the opening through which blood flows. It is desirable to cover as little as possible of the natural opening of the heart with the sewing ring and valve mechanism.

A valve according to the present invention improves on the prior art by providing a more easily removable valve member, as well as maximizing the open bore of the heart valve.

A prosthetic heart valve according to the present invention comprises a sewing ring and removable valve member. The sewing ring is designed for permanent attachment to heart tissue. The valve member is formed for slidable engagement in a central bore of the sewing ring. The valve is then fixed in place in the ring by attachment means such as sutures.

The valve member is removed by inserting a scalpel between the sewing ring and the valve member and cutting a circular path between the two. The scalpel cuts any tissue ingrowth and the attaching sutures so that the valve member may be slid out of the sewing ring. A replacement valve member is then slidably mounted in the attached sewing ring and is connected by suture means.

The sewing ring is formed from a generally cylindrical main ring which is provided with two annular grooves in the outer wall. The grooves are preferably shoulders at the edges of the main ring. First and second O-rings are sized to engage in the first and second grooves.

A cloth, which is preferably tubular, is mounted over the main ring. First and second O-rings are mounted over the cloth in the grooves. The cloth is then folded over the O-rings and sewn to itself so that the O-rings are held against the main ring.

A scalpel is disclosed for cutting tissue and sutures between the sewing ring and the valve member. The scalpel has first and second cutting edges so that cutting may be done in either direction. The scalpel is sized for fitting in the narrow circular path between the sewing ring and the valve member.

In one form the scalpel includes a bend of approximately 60 degrees so that the scalpel may be employed on sewing rings mounted in the mitral position.

A prosthetic heart valve constructed according to the present invention solves many of the problems associated with prior art heart valves. The previous recognition that a two piece replaceable valve is desirable has proven difficult to implement. Tissue ingrowth in the heart has prevented full realization of the hope for removable two piece valves. The present invention provides novel apparatus and method for separating the valve member from the tissue ingrowth so that removal from the sewing ring is eased.

The sewing ring employed in the present invention has a narrow wall profile which maximizes the open area available for mounting the valve member. The larger opening available for the valve member means that there is a larger area available for blood flow within the valve member. This maximization of valve size and bore opening improves hemodynamics.

An embodiment of the invention will now be described by way of example only and with reference to the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is an exploded perspective view of a sewing ring according to the present invention.

Fig. 2 is a side view, partially cutaway, of the main ring and first and second O-rings of the sewing ring of Fig. 1.

Fig. 3 is a cross sectional view taken on line 3-3 of Fig. 2.

Fig. 4 is a perspective view of the sewing ring of Fig. 1, partially assembled.

Fig. 5 is a perspective view of the completed sewing ring of the type illustrated in Figs. 1-4.

Fig. 6 is a cross sectional view taken on line 6-6 of Fig. 5.

Fig. 7 is a side elevational view of a blank for a stent.

Fig. 8 is a perspective view of a completed stent made of the blank of Fig. 7 being mounted by sutures in the sewing ring of Figs. 1-6.

Fig. 9 shows a completed valve after mounting as shown in Fig. 8.

Fig. 10 shows a scalpel designed for removing the stent from the sewing ring after implantation.

Fig. 11 is a side view of the scalpel of Fig. 10.

Fig. 12 is a side view of a second form of scalpel.

Fig. 13 is a cross sectional view taken on line 13-13 of Fig. 10.

Fig. 14 is a perspective view showing the scalpel of Fig. 10 in operation on the valve of Fig. 9.

A sewing ring 20 constructed according to the present invention comprises a main ring 22, cloth 24 and first and second O-rings 26 and 28, respectively. Main ring 22, in this embodiment, is a short cylinder having an inside wall 30, forming bore 31 free of inwardly directed protrusions, and outer wall 32. Main ring 22 has first and second shoulders or grooves 34 and 36, respectively. First and second shoulders 34 and 36 are sized to receive first and second O-rings 26 and 28, respectively.

Main ring 22 carries means for attaching heart valves. In the illustrated embodiment, this includes three pairs of slots 38-43.

Main ring 22 is preferably made of cobalt material, such as Stellite 25 (Trade Mark). Other biocompatible metals such as titanium may also be used. Of course, the size, both in diameter and height of the cylinder, varies with the application. For example, mitral valve rings preferably employ a wider cylinder than aortic valve rings.

The thickness of material used in main ring 22 is approximately .020 inch (0.51mm). The ring is manufactured by conventional methods such as machining it out of a bar of metal or by cutting a tube. Shoulders 34 and 36 are machined in.

Slots 38-43 are preferably cut in main ring 32 by electrical discharge machining (EDM). Other methods could be used to cut slots 38-43, such as lasers. After cutting, the edges of slots 38-43 are polished so as not to cut sutures inserted through them. All edges are contoured so as to provide a rounded running surface for sutures.

Cloth 24 is preferably a cylinder of material such as Dacron® or Teflon®. Any of the various well known materials used in the industry for sewing valves may be employed in practising the present invention.

Assembly of sewing ring 20 is illustrated by the partially assembled view in Fig. 4. Main ring 22 is positioned inside cloth tube 24. The exact positioning of main ring 22 longitudinally within cloth 24 depends upon the application. O-rings 26 and 28 are slid over the outside of cloth tube 24 until they engage shoulders 34 and 36, respectively.

In Fig. 4, O-ring 26 is shown in place. The outline of main ring 22 is shown in dotted lines in Fig. 4. O-ring 28 is shown in position to be mounted over cloth 24.

After the mounting of O-rings 26 and 28, cloth 24 is inverted over O-ring 26 and stitched to itself as illustrated by stitch 44 in Fig. 6. The opposite end of cloth 24 is inverted over O-ring 28 and stitched to itself as illustrated by stitch 46 in Fig. 6. This locks O-rings 26 and 28 in place on shoulders 34 and 36, respectively.

The ends of cloth 24 are turned in and stitched in place to form what is sometimes known in the industry as the sewing ring. This protrusion is used to sew the assembled ring 20 to tissue.

In certain applications, such as the mitral position, a larger sewing protrusion is needed. In these cases, as in the illustrated embodiment, filler or pad 48 is added. Pad 48 may be any of the common sewing ring materials such as foam or batting material. Pad 48 is circumferentially placed around main ring 22 outside of cloth 24. Cloth 24 is then wrapped, as illustrated in Fig. 6, around pad 48 and stitched in place by stitches 50. In this embodiment, stitches 44 and 46 may be basting stitches which are removed once O-rings 26 and 28 are firmly held in place by stitches 50. Various standard stitching techniques may be used to fix cloth 24 around O-rings 26 and 28.

Fig. 5 illustrates a completed sewing ring of the type having a pad 48.

The sewing ring of the present invention may be used with various removable valve mechanisms constructed according to the present invention. Either mechanical or tissue valves may be employed. The illustrated valve mechanism is a tissue valve 60. Valve 60 comprises stent 61 which is covered by cloth 62. Cloth 62 may be any of the various materials used for cloth 24. The stent 61 is formed of an Elgiloy® plate 64, illustrated in flat form in Fig. 7. Construction of stent 61 employs manufacturing techniques disclosed in United States Patent No. 4,680,031. Plate 64 is formed into a cylinder to define a cylindrical outer surface corresponding to and spaced from the cylindrical inner surface 31 of the sewing ring 20, and free of outwardly directed protrusions; plate 64 is covered with cloth 62 as illustrated. Plate 64 has three commissureposts 66, each carrying a mounting hole 68. Along upper edge 70 of plate 64 lie suturing holes 72 and three

pairs of attachment slots 74. Holes 68 and 72 are used when sewing the fabric covering over the stent.

Also provided on plate 64 are attachment means for mounting stent 61 in sewing ring 20. In the illustrated embodiment, the attachment means includes three pair of slots 76-81 which are positioned to align with slots 38-43, respectively, in sewing ring 20. Slots 76-81 are used when the valve is configured for use in the mitral position. When used in the aortic position the valve is inserted into the sewing ring from the left in Figs. 8 and 9 and the sutures are provided in slots 74 as slots 76-81 will not be accessible.

In the illustrated embodiment, the attachment means further includes three double needle suture sets 82, 84 and 86. The sets comprise suture pairs 88, 90 and 92, respectively, and needle pairs 94, 96, 98 (not illustrated), 100 (not illustrated), 102 and 104, respectively.

The illustrated stent is designed for mounting a tissue valve, such as a porcine valve. The invention may also be practised by configuring a mechanical valve in this shape for slidable mounting, with attachment means suitable for connecting to sewing ring 20. The interchangeability of tissue and mechanical valves is an advantage of this system. For example, in certain situations it is not possible to give anticoagulants to the patient because of pregnancy or other physical conditions. Since anticoagulants are normally prescribed in conjunction with implantation of a mechanical valve, a tissue valve is usually used in these situations. At a later time when anticoagulants may be administered, the tissue valve may be replaced with a mechanical valve.

Using the present invention, mechanical and tissue valves may be interchanged using the permanently implanted sewing ring 20. In situations where the conditions requiring a tissue valve no longer exist, a mechanical valve may be used as a replacement.

For construction of a two piece valve according to the present invention, valve member 60 is positioned relative to sewing ring 20, as illustrated in Fig. 8. Needles 94 and 96 are inserted through slots 42 and 43 in sewing ring 20, as illustrated. Needles 98 and 100 (not illustrated) are inserted through slots 38 and 39. Needles 102 and 104 are then inserted through slots 40 and 41 in ring 20. The needles 94-104 are then pulled up to snug the sutures 82-86 down while valve member 60 is inserted in sewing ring 20.

It is important that valve members such as stent 61 not be allowed to pass through sewing ring 20. Means are provided to prevent movement of stent 61 past the point of alignment in valve 20. In the present invention, stitch 108 is taken in cloth 62 around the circumference of valve 60, as illustrated in Fig. 8. This forms a ridge so that valve 60 cannot pass through sewing ring 20. Of course, other embodiments may be used to prevent excess movement of a valve member into stent 20. For example, the cylinder of stent 61 may be tapered to prevent movement through ring 20.

Stent 61 is sized relative to the sewing ring 20 so that slots 76-81 of stent 61 align with slots 38-43 of sewing ring 20. Thus, when suture sets 82, 84 and 86 are tightened, all slots are in proper alignment. The suture sets 82, 84 and 86 are tied tightly and trimmed, as illustrated in Fig. 9. Valve member 60 is now firmly mounted in sewing ring 20.

Implantation in the heart is by known prior art methods. Cloth 24, including pad 48 if present, is sewn to the heart to hold sewing ring 20 in place. As is well known in the art, tissue grows over cloth 24 to further fix sewing ring 20 in place.

Tissue may grow around the union between valve 60 and sewing ring 24 as part of the body's natural process of covering foreign objects. In order to remove valve member 60 of the two-piece valve, it is necessary to remove any tissue ingrowth. Such removal is much eased by a scalpel 110 constructed as described below.

Scalpel 110 is preferably formed from stainless steel. It includes a handle 112 and blade 113. Two configurations are designed for use with valves for different applications. Scalpel 110, as illustrated, is useful to remove the aortic valve and the inferior portion of the mitral valve. A second form 114 includes a bend of approximately a 60° angle between handle 116 and blade 118. This angled scalpel 114 is used for the posterior portion of the mitral valve. The blade is sized to fit between sewing ring 20 and valve member 60, and is preferably less than .005 inches (0.13mm) thick.

Blade 113 includes first and second edges 120 and 122 so that blade 113 cuts in either direction. Blade 113 is tapered slightly and sized sufficiently thin so that it can follow the circular path between wall 30 of sewing ring 26 and valve member 60.

As illustrated in Fig. 14, in use scalpel 110 is slipped between valve member 60 and sewing ring 20. Scalpel 110 is slowly worked around the circumference of valve 60. In the process, scalpel 110 cuts any tissue ingrowth which is formed around the union of valve 60 and sewing ring 20. Scalpel 110 also cuts suture pairs 82, 84 and 86. Valve 60 may then be easily slid out of sewing ring 20. Other means may be used to cut tissue from between sewing ring 20 and valve member 60, such as a laser cutter.

In order to simplify the insertion process, marking means are included for alignment of valve member 60 with sewing ring 20. In the illustrated embodiment, the marking means is a line 130 on

the valve member 60 which aligns with a line 132 on sewing ring 20. Other marking means could be used such as notches in stent 61 of valve member 60 and sewing ring 20.

Claims

1. A heart valve comprising a valve member (60) removably engageable with a sewing ring (20), wherein said sewing ring defines a cylindrical inner surface (30) and said valve member has a cylindrical outer surface corresponding to the cylindrical inner surface of said sewing ring, characterised in that said inner surface of said sewing ring is spaced from said outer surface of said valve member, said inner and outer surfaces of said sewing ring and said valve member, respectively, being free of inwardly and outwardly directed protrusions, respectively, and said valve member being attachable to said sewing ring by means of sutures (82,84,86), whereby said valve member may be removed from said sewing ring by passage of a blade circumferentially around said valve member in the space between said valve member and said sewing ring.

2. A valve as claimed in claim 1 comprising slots (38-43) on the sewing ring for receiving sutures; and sutures (82,84,86) on the valve member generally adjacent the slots when the valve member is mounted in the sewing ring.

3. A valve as claimed in claim 2 wherein the slots comprise pairs of openings and the sutures are in pairs, each suture of a pair having a needle.

4. A valve as claimed in claim 1 comprising sutures (82,84,86) extending through the wall of the valve means and slots in the sewing ring for receiving the sutures whereby knots on the sutures outside of the sewing ring hold the valve means in place within the sewing ring.

5. A valve as claimed in any preceding claim wherein said sewing ring (20) has a main ring (22) forming a central bore (31), the ring having an inner surface (30) towards the central bore and an outer surface (32), the outer surface including two annular grooves (34,36);

first and second O-rings (26,28) sized to fit the two grooves on the main ring; and

cloth (24) for forming a sewing ring, mounted by first surrounding the ring, then by having the cloth held to the ring by mounting the first and second O-rings over the cloth, and the cloth being sewn in place around the O-rings on the outer surface of the ring.

Patentansprüche

1. Herzklappe mit einem Klappenteil (60), das austauschbar in Eingriff mit einem Nähring (20) bringbar ist, wobei der genannte Nähring eine zylindrische Innenfläche (30) festlegt und das genannte Klappenteil eine zylindrische Außenfläche aufweist, die der zylindrischen Innenfläche des genannten Nährings entspricht, dadurch **gekennzeichnet**, daß die genannte Innenfläche des genannten Nährings zur genannten Außenfläche des genannten Klappenteils einen Abstand aufweist, die innere und äußere Oberfläche des genannten Nährings bzw. des genannten Klappenteils frei sind von nach innen bzw. nach außen gerichteten Vorsprüngen, und das Klappenteil am Nähring mittels Nähten (82, 84, 86) anbringbar ist, wobei das genannten Klappenteil vom genannten Nähring dadurch entfernt werden kann, daß man eine Klinge in Umfangsrichtung rund um das Klappenteil im Raum zwischen dem genannten Klappenteil und dem genannten Nähring hindurchführt.

2. Klappe nach Anspruch 1, mit Schlitzen (38-43) am Nähring zur Aufnahme von Nähten; und mit Nähten (82, 84, 86) am Klappenteil, die im allgemeinen den Schlitzen benachbart sind, wenn das Klappenteil am Nähring angebracht ist.

3. Klappe nach Anspruch 2, worin die Schlitze Paare von Öffnungen aufweisen und die Nähte paarweise vorliegen, wobei jede Naht eines Paares eine Nadel aufweist.

4. Klappe nach Anspruch 1, mit Nähten (82, 84, 86), die sich durch die Wand der Klappenreinrichtung hindurch und Schlitze im Nähring hindurch erstrecken, um die Nähte aufzunehmen, wobei Knoten an den Nähten außerhalb des Nährings die Klappeneinrichtung in ihrer Lage innerhalb des Nährings halten.

5. Klappe nach irgendeinem vorangehenden Anspruch, wobei der genannte Nähring (20) einen Hauptring (22) aufweist, der eine mittige Bohrung (31) bildet, wobei der Ring eine Innenoberfläche (30) zur mittigen Bohrung hin und eine Außenoberfläche (32) aufweist und die Außenfläche zwei Ringnuten (34, 36) umfaßt;

einen ersten und zweiten O-Ring (26, 28), die so bemessen sind, daß sie zu den beiden Nuten am Hauptring passen; und

ein Tuch (24) zum Bilden eines Nährings, das dadurch angebracht wird, daß es zuerst den Ring umgibt, dann das Tuch am Ring

gehalten wird, um den ersten und zweiten O-Ring über dem Tuch anzubringen, und das Tuch in seiner Lage rund um die O-Ringe auf einer Außenfläche des Ringes angenäht wird.

Revendications

1. Valve cardiaque comprenant un élément de valve (60) qui peut être fixé de façon amovible avec un anneau à coudre (20), dans laquelle ledit anneau à coudre définit une surface interne cylindrique (30) et ledit élément de valve possède une surface externe cylindrique qui correspond à la surface interne cylindrique dudit anneau à coudre, caractérisée en ce que ladite surface interne dudit anneau à coudre est espacée de ladite surface externe dudit élément de valve, lesdites surfaces interne et externe dudit anneau à coudre et dudit élément de valve, respectivement, étant libre de saillies dirigées vers l'intérieur et vers l'extérieur respectivement, et ledit élément de valve pouvant être fixé audit anneau à coudre à l'aide de sutures (82, 84, 86), de sorte que ledit élément de valve peut être retiré de ledit anneau à coudre en passant une lame circonférentiellement autour dudit élément de valve, dans l'espace compris entre ledit élément de valve et ledit anneau à coudre.

2. Valve selon la revendication 1, comprenant des fentes (38 à 43) prévues sur l'anneau à coudre pour recevoir des sutures ; et des sutures (82, 84, 86) prévues sur l'élément de valve dans une position sensiblement adjacente aux fentes lorsque ledit élément de valve est monté dans l'anneau à coudre.

3. Valve selon la revendication 2, dans laquelle les fentes comprennent des paires d'ouvertures et les sutures sont prévues par paires, chaque suture d'une paire comprenant une aiguille.

4. Valve selon la revendication 1, comprenant des sutures (82, 84, 86) qui s'étendent à travers la paroi de la valve et des fentes pratiquées dans l'anneau à coudre pour recevoir les sutures, de sorte que des noeuds pratiques sur les sutures à l'extérieur de l'anneau à coudre maintiennent la valve en place dans l'anneau à coudre.

5. Valve selon une quelconque des revendications précédentes, dans laquelle ledit anneau à coudre (20) comprend un anneau principal (22) formant une lumière centrale (31), l'anneau ayant une surface interne (30) dirigée vers la lumière centrale et une surface externe (32), la surface externe présentant deux gorges annulaires (34, 36) ;

des première et seconde bagues toriques (26, 28) dimensionnées pour s'ajuster dans les deux gorges de l'anneau principal ; et

une étoffe (24) utilisée pour former un anneau à coudre, que l'on monte en entourant tout d'abord l'anneau puis en retenant le tissu sur l'anneau en montant les première et seconde bagues toriques par dessus l'étoffe, et l'étoffe étant cousue en place autour des bagues toriques sur la surface externe de l'anneau.

Fig. 1

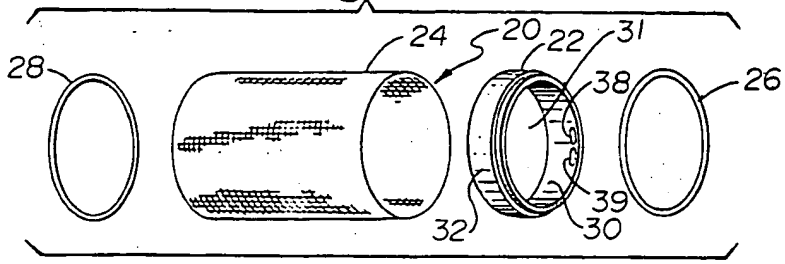

Fig. 2

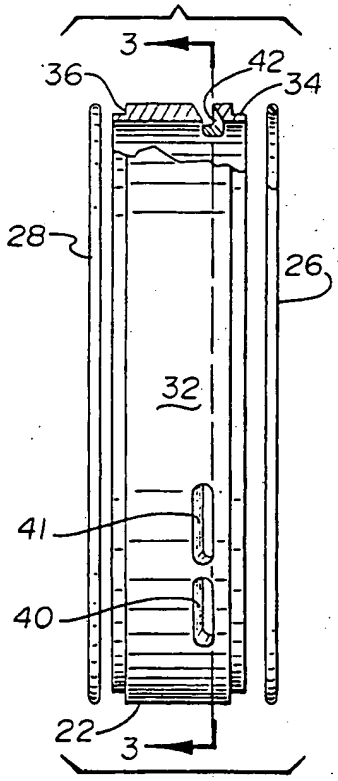

Fig. 3

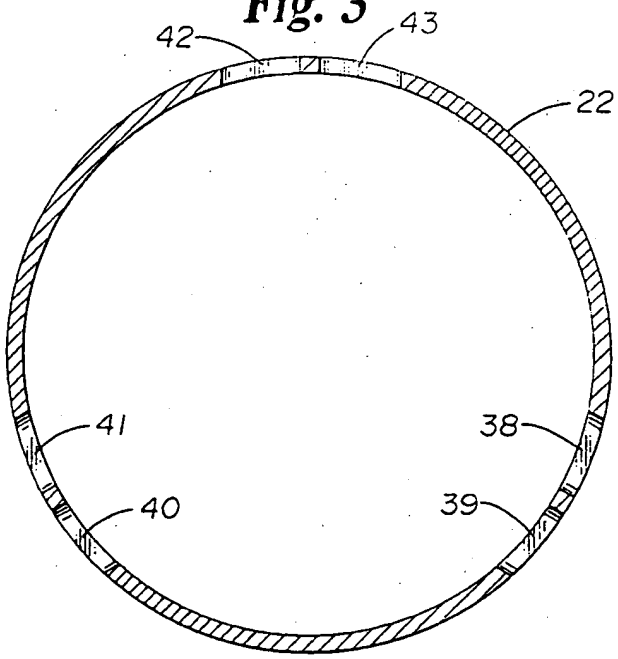

Fig. 4

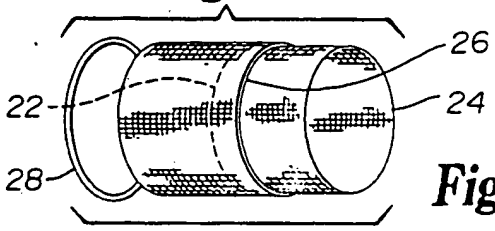

Fig. 5

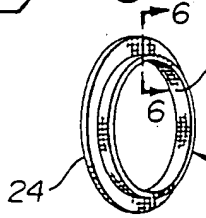

Fig. 6

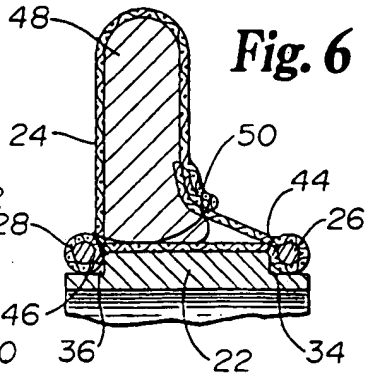

Fig. 7

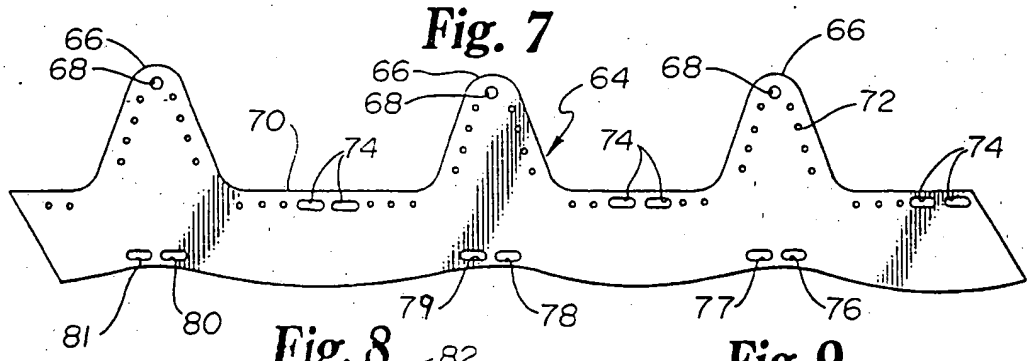

Fig. 8

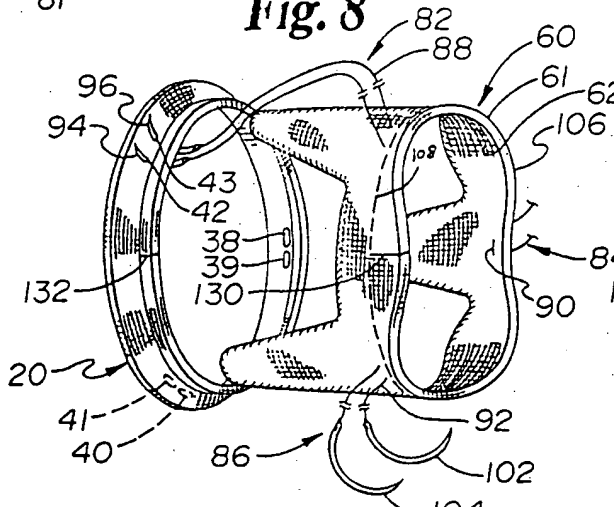

Fig. 9

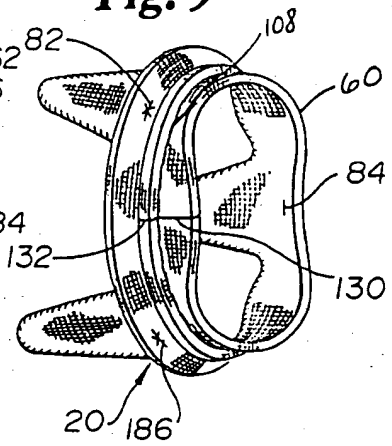

Fig. 10

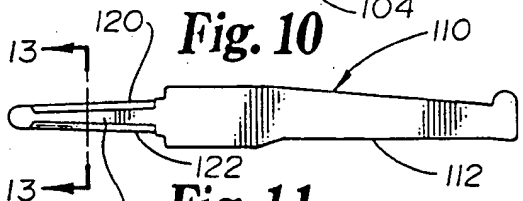

Fig. 11

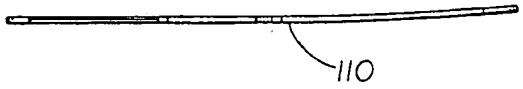

Fig. 12

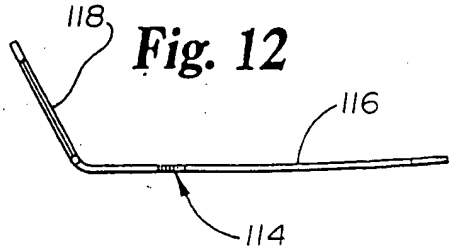

Fig. 13

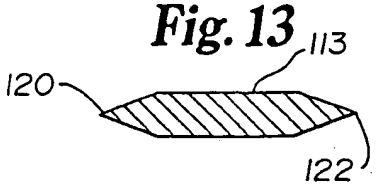

Fig. 14